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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/727,021	12/02/2003	Timothy W. Lovenberg	JJPR-0043	5495

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EXAMINER

HAMUD, FOZIA M

ART UNIT PAPER NUMBER

1647

DATE MAILED: 12/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/727,021

Applicant(s)

LOVENBERG ET AL.

Examiner

Fozia M. Hamud

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24,25,27,28,34-36 and 40-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-25, 27-28, 34-36, 38, 40-54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Response to Amendment

1a. Receipt of Applicants' amendment and arguments filed on 05 October 2005 is acknowledged.

Status of Claims:

1b. Claims 1-23, 26, 29-33, 37, 39 have been cancelled and new claims 41-54 have been added. Thus, claims 24, 25, 27-28, 34-36, 38 and 40-54 are pending, and under consideration.

1c. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior office action.

2. The following previous objections and rejections are withdrawn in light of Applicants amendment filed 10/05/2005.

(I) All of the rejections of cancelled claims 26, 29-33, 37 and 39 are moot.

(II) The rejection of claims 24, 27, 34-36, 38 and 40 made under 35 U.S.C. 12, first paragraph, for not complying with the written description provision of this statute is withdrawn, because these claims now recite appropriate sequences.

(III) The rejection of claims 24, 26, 27, 36, 38 and 40 made under 35 U.S.C. 12, first paragraph, for not enabling the full scope of the claimed invention, is withdrawn, because these claims now recite appropriate sequences.

(IV) The rejection of claims 24-36, 38 and 40, made under 35 U.S.C. § 112, second paragraph, as being indefinite is withdrawn. Applicants' argument that one skilled in the art would understand the hybridization conditions under which homologues of human

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histamine H3 receptor could be identified using DNA that encoded the polypeptide of SEQ ID NO:7, is found persuasive.

(V). The rejection of claims 24, 27 made under 35 U.S.C § 102(e) as being anticipated by U.S Patent No: 5,882,893 (Goodearl et al. published 16 March 1999; effective filing date 04 December 1997), is withdrawn. The Goodearl et al reference does not disclose a method of using a nucleic acid encoding the polypeptide of SEQ ID NO:7, to isolate DNA encoding a homologue of human histamine H3 receptor, and isolating homologue of human H3 receptor that retains the biological activity of the polypeptide of SEQ ID NO:7.

New Rejections:

3a. Claims 24, 27, 34-35, 38, 40 and 53-54 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of using a nucleic acid encoding the polypeptide of SEQ ID NO:7 to isolate or produce a homologue of human histamine H3 receptor that binds to the specific ligands recited on claims 36, 42, 46, 50 and exhibit the biological activities recited on claims 41, 43-45, 47-51, does not enable a method isolating or producing a homologue of human histamine H3 receptor that has greater or reduced affinity for "all possible" ligands, than the human histamine receptor H3 of SEQ ID NO:7, or exhibit "all possible" biological activities of the human histamine receptor H3 of SEQ ID NO:7.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

With respect to the recitation of "biological activity" in the claims, Applicants' argument that the specification teaches how to identify said activities, is not found persuasive, because Applicants are arguing limitations not recited in the claims. Applicants are correct that the specification discloses how to monitor or identify histamine H3 receptor activities, and new claims 41, 43-45, 47-51 recite said specific activities. However, claims 24, 27, 38, 40 and 54 encompass "all possible biological activities". Regarding claims 34 and 35, the recitation of "a ligand", encompasses "all possible ligands", while the specification discloses specific ligands for the polypeptide of SEQ ID NO:7. Claims 36, 42, 46, 50, recite specific ligands for the polypeptide of SEQ ID N:7. Therefore, due to the lack of direction/guidance presented in the specification regarding "all possible ligands" and "all possible biological activities", the complex nature of the invention, and the breadth of the claims, which fail to recite particular biological activities, undue experimentation would be required of the skilled artisan to practice the claimed invention in its full scope. In the absence of more guidance, one skilled in the art would have to proceed with undue trial and error experimentation to screen through a vast number of ligands to identify homologues of human histamine H3 receptor that retain the desired specific biological of SEQ ID NO: 7.

Claim Rejections - 35 U.S.C. § 112, second paragraph:

4. Claims 24-25, 27-28, 34-36, 38 and 40-54 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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4a. Claims 24, 25, 27, 28, 38, and 40, recite the article "an or a" when referring to a specific polypeptide or nucleic acid. For example, claim 24 recites in line 4 and line 13 "...**an** amino acid sequence of SEQ ID NO:7....", however, this renders the claim vague and indefinite, because it is unclear whether only part of the polypeptide of SEQ ID NO:7 is being referred to. Likewise, claim 24, sub-part (b) recites "...encoding **a** human histamine receptor...", although this section of the claim is referring to specific one. It is suggested that the claims be amended to recite the article "**the**", when referring to a specific sequence, for example ".....the amino acid sequence of SEQ ID NO:7....". Appropriate correction is required.

Claims 34, 35, 36, 41-54 are rejected in so far as they depend on claims 24, 27, 38 or 40 for the limitations set forth above.

Conclusion:

5. No claim is allowed.

The claims are free of the prior art of record.

Advisory Information:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia M. Hamud whose telephone number is (571) 272-0884. The examiner can normally be reached on Monday, Thursday-Friday, 6:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G. Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Fozia Hamud
Patent Examiner
Art Unit 1647
08 December 2005



JOSEPH MURPHY
PATENT EXAMINER